

REMARKS/ARGUMENTS

Claims 1-3, 6-10 and 12-13 are pending in the instant application. Favorable reconsideration is kindly requested.

Drawing Objections

The Office Action includes an objection to the drawings as failing to illustrate a “second flexible membrane” and a “penetrating injection component”. Applicant respectfully traverses the objection.

The claims do not recite any structure using the nomenclature “penetrating injection component”. Rather, claim 1, for example, recites “the injection component penetrating the first and second flexible membranes”. This is the only instance of “penetrating” in any currently pending claim. “Penetrating” is used in claim 1 in the adverb sense, rather than as an adjective. Moreover, the specification already provides ample support and reference to an “injection component”, namely reference numeral 11, specification p. 3, line 20 and *passim*.

However, and without limitation of the claims, Figs. 2a and 3, which include depiction of the injection component (11) are amended to include specific reference to a needle thereof, ref. 25. The drawings and specification are amended only to add reference numeral 25 for indication of the needle. However, as the specification itself makes clear, the needle is merely exemplary of the injection component. See, for example, p. 5, lines 4-7, which states

... the injection port 7 may be opened by means of an injection component, for example by penetrating the membrane by means of an injection needle for enabling injection when so is desired.

(Spec. p. 5, lines 5-7)

The “second flexible membrane”, is illustrated, for example at Figs. 2a, 3, as originally filed, and disclosed in the specification, for example at para. [0022], [0023], as originally filed. The drawings and specification are amended only to add reference numeral 24 indicating the second flexible membrane.

No new matter has been added by these amendments. In light of the amendments and these remarks, favorable reconsideration and withdrawal of the objection is kindly requested.

Response to Arguments

Applicant gratefully acknowledges the withdrawal of the prior rejection of claims 1-3 and 6-10 as allegedly obvious over Schock, taken alone, in view of Applicant's response filed January 7, 2009. Claim 12 was first presented in the January 7, 2009 amendment, and was not the subject of any prior rejection.

Rejection under 35 U.S.C. § 103

Claims 1-3, 7-10 and 12-13 are rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,632,735 to Wyatt, *et al.* ("Wyatt"), in view of U.S. Patent No. 5,685,866 to Lopez ("Lopez"). Applicant respectfully traverses the rejection, for at least the following reasons.

Independent claim 1 recites

A device for injection, comprising a body provided with a first channel for conveyance of a first medical substance and a first connecting component having a first port for introduction of a first medical substance into said first channel, said first connecting component being connectable to an external unit, and a second channel for conveyance of a second medical substance and a second connecting component having a second port that is sealed by a first flexible air- and liquid-proof membrane, which can be opened by means of an injection component for injecting a second medical substance into said second channel, wherein said first flexible air- and liquid-proof membrane sealing said second port cooperates with a second flexible membrane arranged in an injection component which is connectable to said second connecting component, and the device has means for holding said second flexible membrane with a pressure against said first flexible air- and liquid-proof membrane, the injection component penetrating the first and second flexible membranes, and the body is provided with a third connecting component being common to the first and the second channels and having at least one third port for conveying medical substances out from said first and second channels, whereby said first, second and third connecting components and the body are an integrated unit, and wherein the first channel extends in a generally straight line through the body of the device.

The Office Action acknowledges that Wyatt does not teach an injection component with either a second flexible membrane or a penetrating member. It proposes that it would have been obvious to combine Wyatt with Lopez to provide the admittedly missing features, as "a matter of simple

substitution of two known equivalents in the art.” Office Action, p. 4. Applicant respectfully disagrees.

The Office Action incorrectly presumes that the only distinguishing feature of the device of claim 1 hereof over the features of the device disclosed by Wyatt is that Wyatt does not teach an injection component with a second membrane and penetrating member. The apparatus according to claim 1 differs from the device shown in Figure 8 of Wyatt in that the blunt cannula C of Wyatt's device is arranged to penetrate the split septum 27 while the device is being assembled (See col. 7, lines 39-47; which state that each connector M is interconnected with the device 65 by urging the cannula into the split septum 27.) Once the device has been assembled and is ready for use, the split septum 27 does not seal the channel containing it, *i.e.*, the seal is broken on interconnecting connector M.

On the contrary, the device according to claim 1 hereof, in its assembled and ready-to-use state, comprises a (second) channel that is sealed by a first flexible membrane. An injection component (11) comprising a second flexible membrane (25) may be connected to the device and the first and second membranes may be held against each other with a pressure until a user decides to penetrate the first and second membranes using an injection component (11), *i.e.* the first and the second flexible membranes of the device according to claim 1 are selectively penetrable.

Furthermore, nothing in either Wyatt or Lopez teaches or suggests to the ordinarily skilled person in the art that the use of two membranes provides any benefit or advantage, for example during fluid transfer. The apparatus recited in claim 1 presses the two flexible membranes of the device together. One result is that fluid cannot be pressed out past the contact surfaces of the membranes and a sealed connection is obtained while an injection component is penetrating the two flexible membranes. Wyatt and Lopez do not teach a skilled person to establish such a sealed connection. Instead, both documents disclose a piercing member (cannula C in Wyatt and spike 24 in Lopez) that pierces a single membrane.

The Office Action proposes that it would have been obvious “as a matter of simple substitution” to replace the injection components of Wyatt with those of Lopez. Even presuming that the references were to be combined as proposed, a skilled person faced with the teachings of Wyatt and Lopez would therefore be prompted to replace (or substitute) both the injection component, M, and the septum-holding arrangement (24) including the split septum (27) in the

device disclosed by Wyatt with the spike (24) and flexible membrane (36) disclosed by Lopez, thereby having a device comprising only one membrane. It remains well-settled that to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

Therefore, Applicant respectfully submits that independent claim 1 is patentably distinguished over Wyatt and Lopez, taken singly or in combination.

Claims 2-3, 7-10 and 12-13 are included in the statement of the rejection (Office Action, p. 3). However, the text of the Office Action does not set forth any *prima facie* case that the feature of claims 2-3, 7-10 and 12-13 are either taught or suggested in Wyatt or Lopez, singly or in combination. An Office Action violates 35 U.S.C. § 132 if it "is so uninformative that it prevents the applicant from recognizing and seeking to counter the grounds for rejection." *Chester v. Miller*, 906 F.2d 1574, 1578, 15 USPQ2d 1333, 1337 (Fed. Cir. 1990). Therefore, applicant respectfully submits that the rejection of claims 2-3 and 7-10 are poorly taken, and kindly requests favorable reconsideration and withdrawal.

Moreover, with specific reference to independent claim 13, this claim recites "a second port, that is sealed by a first flexible air- and liquid-proof membrane lacking any pre-existing opening therethrough". At least this feature of claim 13 is plainly not present in Wyatt, the base reference upon which the Office Action relies to read a first flexible membrane. The Wyatt membrane (27) includes a slit therethrough. *See, e.g.*, Figs. 7, 8D; "split septum 27", Col. 6, line 4.

In light of the foregoing, Applicant respectfully submits that that rejection of claims 1-3, 7-10 and 12-13 has been overcome, and requests favorable reconsideration and withdrawal.

Conclusion

In light of the foregoing, Applicant respectfully submits that all claims are patentable, and further that the instant application is in condition for allowance. An early and favorable Notice of Allowability is kindly solicited.

THIS CORRESPONDENCE IS BEING
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RCF/DJT:lf/lac

Respectfully submitted,



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